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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/510,937 02/22/00 CAMPBELL

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HM12/0920

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EXAMINER

MOHAMED, A

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

09/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Applicati n N .

09/510,937

Applicant(s)

CAMPBELL ET AL.

Examiner

Abdel A. Mohamed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/29/01 has been entered.

ACKNOWLEDGMENT OF AMENDMENT, REMARKS, TERMINAL DISCLAIMER AND STATUS OF THE CLAIMS

2. The amendment, remarks and terminal disclaimer (TD) filed 6/29/01 are acknowledged, entered and considered. In view of Applicant's request claim 1 has been amended. Thus, claims 1-9 are now pending in the application. The rejections under 35 U.S.C. 112, second paragraph and 35 U.S.C. 102(b) are withdrawn in view of Applicant's amendment and remarks filed 6/29/01. However, the rejections under the judicially created doctrine of double patenting and 35 U.S.C. 103(a) over the prior art of record are maintained.

HEADING FOR NONSTATUTORY DOUBLE PATENTING

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

DOUBLE PATENTING, NON-STATUTORY WITH PATENTS

4. Claims 1-9 remain rejected under the judicially created doctrine of double patenting over claims 1-22, 1-40 and 1-2, respectively of U. S. Patent Nos. 6,027,779, 6,025,044 and 6,027,811, respectively since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patents.

The subject matter claimed in the instant application is fully disclosed in the patents and is covered by the patents since the patents and the application are claiming common subject matter, as follows: The instantly claimed invention and the patents teach a PTFE tube with specific

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architecture and structure in which a thin-wall may be used in a non-porous embodiment as the balloon portion of a balloon catheter (See e.g., col. 9, lines 7-16; col. lines 57 to col. 10, lines 5; Figures 16A and 16B and 20 of U.S. Patent No. 6,027,779)..

CLAIMS REJECTION-35 U.S.C. 103(a)

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Buck et al. (U.S. Patent No. 4,925,710) in view of Gore (U.S. Patent No. 3,953,566) and Soltesz (U.S. Patent No. 5,254,107).

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The independent claim 1 as amended on 6/29/01 is drawn to a non-porous catheter balloon comprising permeable, porous expanded polytetrafluoroethylene (ePTFE) having a microstructure of nodes interconnected by fibrils and provided with a non-porous coating over the ePTFE to render the balloon non-porous. The dependent claims 2-3 and 8-9 are drawn to particularly to non-porous coating comprising fluorinated ethylene propylene (claim 2), multiple layers of porous PTFE (claim 8), continuous coating (claim 9), and an adhesive (claim 3), wherein the adhesive comprises a thermoplastic adhesive (claim 4), wherein the thermoplastic adhesive is a thermoplastic fluoropolymer (claim 5), wherein the porous PTFE comprises ePTFE (claim 6) and wherein the balloon is an inelastic balloon (claim 7).

Buck et al. disclose a thin-wall non-porous tube comprising porous PTFE and a non-porous coating comprising polymers such as fluorinated ethylene propylene and commercially available thermoplastic adhesives such as thermoplastic fluoropolymers (See e.g., col. 2, lines 49 to col 3, lines 46). Although, on column 7, lines 10 to 13, the reference states that the nature or number of the layers in the outer sheath of the multilayered tube is not critical and can be selected as desired for the particular application contemplated. Nevertheless, the reference clearly discloses the use of non-porous coating comprising multiple layers of porous PTFE as well as the employment of a continuous coating (See e.g. abstract, Example , claims 1 and 16).

Thus, the patent of Buck et al. clearly discloses a thin-wall non-porous tube comprising porous PTFE and a non-porous coating comprising polymers such as fluorinated ethylene propylene and commercially available thermoplastic adhesives such as thermoplastic

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fluoropolymers and the use of non-porous coating comprising multiple layers of porous PTFE as well as the employment of a continuous coating.

The patent of Buck et al. differs from claims 1-9 in failing to teach the use of a porous PTFE tube comprising a porous expanded PTFE (ePTFE) and wherein the balloon is an inelastic balloon. However, the reference of Gore '566 teaches the process for producing porous products of all kinds of shaped articles such as tubes and sheet films of porous expanded PTFE, wherein the PTFE has a microstructure of nodes interconnected by fibrils (See the entire document and particularly the abstract and claims). Further, the patent of Soltesz '107 teaches the construction of catheter tube having a middle layer of wire reinforcement which is enclosed by inner and outer layers which are described as being tubular thermoplastic sections. Thus, the resulting catheter corresponding to the first and second catheter sections exhibits different properties in a manner corresponding to the different properties of thermoplastic materials used (See e.g., col. 3, lines 3-16). Further, on col. 3, lines 40 to 43, the reference clearly states that the inner tubular plastic layer may be made of PTFE or the like. Hence, clearly showing the use of PTFE and thermoplastic material in the construction of catheter tube.

With respect to the structure of the balloon to be an inelastic balloon, although, the prior art does not teach the use or construction of balloon *per se*, however, the prior art clearly teach the use or construction of thin-wall tube comprising porous PTFE and a non-porous coating, and as such, it would be conventional and within the ordinary skill in the art to which this invention pertains to expect the tube to be inelastic because the prior art used the same

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material/composition under substantially the same situation to make the thin-wall catheter tube as the instant claimed thin-wall catheter balloon. Therefore, in the absence of sufficient objective factual evidence or unexpected results to the contrary, it would have been obvious to expect the tube of the prior art to be inelastic tube because of the reasonable expectation of the functional equivalency of the non-porous coating material.

ARGUMENTS ARE NOT PERSUASIVE

DOUBLE PATENTING, NON-STATUTORY WITH PATENTS

6. The rejection of claims 1-9 under the judicially created doctrine of double patenting over claims 1-22, 1-40 and 1-2, respectively of U. S. Patent Nos. 6,027,779, 6,025,044 and 6,027,811, respectively since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patents for the same reasons discussed in the previous Office action. Although, Applicant has corrected the S.N. 08/108,963 and filed a terminal disclaimer (TD) to S.N. 08/486,124, however, the TD is not proper and has not been accepted because the T.D. submitted previously with respect to the issue of obviousness-type double patenting to the parent patents (i.e., Patent No. 6,025,044 and 6,027,779 corresponding to S.N. 08/204,708 and S.N. 08/247,960, respectively) were not entered because of the previously submitted T.D. reciting S.N. 08/108,863 which has not been patented and disclaimed by the owner W. L. Gore & Associates. Inc. Therefore, it is suggested that Applicant file a proper TD disclaiming all parent

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patents together with correct application number corresponding to correct patent number in order to overcome the judicially created doctrine of double patenting.

CLAIMS REJECTION-35 U.S.C. § 103(a)

7. The rejection of claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Buck et al. (U.S. Patent No. 4,925,710) in view of Gore (U.S. Patent No. 3,953,566) and Soltesz (U.S. Patent No. 5,254,107).

Applicant's arguments filed 6/29/01 have been fully considered but they are not persuasive. Applicant has argued that the PTFE of Buck et al. is described as optionally containing fillers such as spherical glass beads as stated on col. 4, lines 48-57 and there is absolutely no indication that the resulting tube is porous through its wall, and as such, the material of the tube wall cannot be considered to be permeable is noted. However, this is irrelevant because the '710 patent of Buck et al. on col. 4, lines 30-32 states that the filler material may come in particles of any shape including spheres, rods, fibers, random angular shapes, etc., Thus, clearly showing that other fillers in various and/or any shape can be used, although, the preferred one is spherical.

Further, the patent of Gore's '566 on col. 1, lines 37-41 clearly states that the porous structure produced by the process of this invention (i.e., process of the patent) is permeable and can be laminated, impergenated, and bonded with other materials (which may include the material of the primary reference of Buck et al.) to provide composite structures having novel and unique properties. Furthermore, on col. 4, lines 55-59, Gore's patent teaches that expanded amorphous-

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locked materials have permeabilities to gases, and to liquids in some cases, which are much higher than the corresponding permeabilities of conventional molded or extruded PTFE. Moreover, the reference of Gore's '566 as discussed above teaches the process for producing products of all kinds of shaped articles such as tubes and sheet films of permeable porous ePTFE, wherein the PTFE has a microstructure of nodes interconnected by fibrils. Thus, clearly suggesting the use of permeable material having interconnected void spaces. Hence, such features are known or suggested in the art, as seen in the secondary reference of Gore, and including such features into a thin-wall non-porous tube comprising porous PTFE and a non-porous coating comprising polymers such as fluorinated ethylene propylene and commercially available thermoplastic adhesives such as thermoplastic fluoropolymers of the primary reference of Buck et al. would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof.

With respect to the structure of the balloon to be an inelastic balloon, although, the prior art does not teach the use or construction of balloon *per se*, however, the prior art of Soltesz '107 as discussed above teaches the use of PTFE and thermoplastic material in the construction of catheter tube. Thus, the combined teachings of the prior art clearly teach the use or construction of thin-wall tube comprising porous permeable ePTFE and a non-porous coating, and as such, it would be conventional and within the ordinary skill in the art to which this invention pertains to expect the tube to be inelastic because the prior art used the same material/composition under substantially the same situation to make the thin-wall catheter tube as the instant claimed thin-wall

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catheter balloon. Therefore, in the absence of sufficient objective factual evidence or unexpected results to the contrary, it would have been obvious to expect the tube of the prior art to be inelastic tube because of the reasonable expectation of the functional equivalency of the non-porous coating material.

Thus, it is the Examiner's position that in view of the combined teachings of the prior art and in view of the above, one of ordinary skill in the art would have been motivated at the time the invention was made to use or easily adapt the already known system of manufacturing ePTFE described in the combined teachings of the prior art for the intended purpose of obtaining a non-porous catheter balloon comprising permeable porous ePTFE provided with a non-porous coating, is an obvious modification of the prior art combined teachings at the time the invention was made. Thus, it is made obvious by the combined teachings of the prior art since the instantly claimed invention which falls within the scope of the prior art teachings would have been obvious because as held in host of cases including *Ex parte Harris*, 748 O.G. 586; *In re Rosselete*, 146 USPQ 183; *In re Burgess*, 149 USPQ 355 and as exemplified by *In re Betz*, "the test of obviousness is not express suggestion of the claimed invention in any and all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them".

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ACTION IS FINAL, FIRST ACTION FOLLOWING REQUEST FOR CONTINUED EXAMINATION UNDER 37 CFR 1.114

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONCLUSION AND FUTURE CORRESPONDENCE

9. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 5:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

AAM Mohamed/AAM

September 18, 2001